

FOLEY & LARDNER  
ATTORNEYS AT LAW  
WASHINGTON HARBOUR  
3000 K STREET, N.W., SUITE 500  
WASHINGTON, D.C. 20007-5109  
TELEPHONE: (202) 672-5300  
FACSIMILE: (202) 672-5399

FAX RECEIVED

NOV 17 2000

PETITIONS OFFICE

## FACSIMILE TRANSMISSION

Total # of Pages 4 (including this page)

TO:	PHONE:	FAX #:
U.S. Patent and Trademark Office Petitions Branch Attn: Karin Tyson	(703) 305 9284	(703) 308 6916

In re Interim Patent Term Extension of U.S. Patent No. 4,373,527  
Patentee: Robert E. Fischell  
Assignee: The Johns Hopkins University  
Issue Date: February 15, 1983

From: Stephen B. Maebius  
Sender's Direct Dial: 202 672 5569  
Date: November 17, 2000  
Client/Matter No: 047711/0100

## MESSAGE:

## Certificate of Transmission

I hereby certify that a Fourth Status Inquiry is being facsimile transmitted to the Patent and Trademark Office on November 17, 2000.

Date

11-17-00

M. K. McDevitt

Maggie K. McDevitt  
Assistant to Stephen B. Maebius

If there are any problems with this transmission or if you have not received all of the pages, please call (202) 672-5304.

Operator:	Time Sent:	Return Original To:
		Maggie K. McDevitt

CONFIDENTIALITY NOTICE: THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS INTENDED ONLY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE DESIGNATED RECIPIENTS NAMED ABOVE. THIS MESSAGE MAY BE AN ATTORNEY-CLIENT COMMUNICATION, AND AS SUCH IS PRIVILEGED AND CONFIDENTIAL. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT OR ANY AGENT RESPONSIBLE FOR DELIVERING IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT YOU HAVE RECEIVED THIS DOCUMENT IN ERROR, AND THAT ANY REVIEW, DISSEMINATION, DISTRIBUTION OR COPYING OF THIS MESSAGE IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL. THANK YOU.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No. 047711/0100

In re INTERIM PATENT TERM EXTENSION OF U.S. Patent No. 4,373,527

Patentee: Robert E. FISCHHELL

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

FAX RECEIVED

NOV 17 2000

PETITIONS OFFICE

FIFTH STATUS INQUIRYAssistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Patentee filed a Status Inquiry on October 13 and 27 and November 3 and 10, 2000, relating to the above-captioned interim extension application. A Request for Reconsideration of Notice of Final Determination of Ineligibility was filed in the U.S. Patent Office on May 8, 2000. The U.S. Patent Office indicated that it is trying to get a response from the FDA to a letter dated March 27, 2000 (copy enclosed), from Ms. Karyn Tyson of the U.S. Patent Office to Mr. David Read of the FDA, so that it can decide how to respond to the Request for Reconsideration. It has more than been 7 months since that letter was sent.

On October 13 and 27 and November 3 and 10, 2000, the patentee filed a status inquiry with the U.S. Patent Office with a copy to Mr. Read at the FDA. On October 19, 2000, the undersigned received a phone call from Ms. Claudia Grillo of the FDA, who indicated that the FDA is in the process of preparing a response to the Patent Office's March 27<sup>th</sup> letter, and that a response should be complete within a couple of weeks. The patentee hereby requests a status report as to the preparation of the FDA's response.

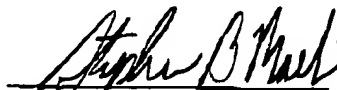
The patentee is required to file a renewed application for interim extension during a period that starts 60 days before the first year interim extension expires (i.e., such renewed application would need to be filed around December 15, 2000), but in this case, patentee has not yet even been granted the first extension, and the first-year period is drawing to a close.

Respectfully submitted,

**NOV 17 2000**

Date

FOLEY & LARDNER  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5109  
Telephone: (202) 672-5569



Stephen B. Maebius  
Attorney for Applicant  
Registration No. 35,264

cc: Mr. David T. Read  
Acting Director Regulatory Policy Staff, CDEV  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, Maryland 20852



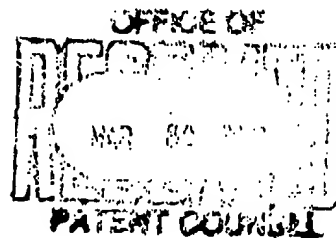
UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

MAR 27 2000

David T. Read  
Acting Director Regulatory Policy Staff, CDEV  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

FAX RECEIVED

NOV 17 2000



Dear Mr. Read:

## PETITIONS OFFICE

The attached application for interim patent term extension of U.S. Patent No. 4,373,527 was filed on January 28, 2000, under 35 U.S.C. § 156(d)(5).

The assistance of your Office is requested in confirming that the product identified in the application, Minimed 2007, is subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g)(3)(B)(ii).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156(d)(5) only if an application under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted prior to January 28, 2000 for the product Minimed 2007.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Francis A. Cooch  
Office of Patent Counsel  
Johns Hopkins University  
Applied Physics Laboratory  
11100 Johns Hopkins Road/Laurel MD 20725-6099

kt